CHARGE: 501(c)—the strength of the article, when shipped and while held for sale, differed from that which it purported to possess, namely, 1/120 grain strychnine sulfate per tablet; 502(a)— the label statements (drum and box) "Strychnine Sulphate 1/120 Gr." were false and misleading; 502(j)—the article was dangerous to health when used in the dosage, or with the frequency or duration recommended in the labeling; and 502(a)—the labeling of the repacked article, while held for sale, contained false and misleading representations and suggestions that the article was an adequate and effective treatment for overcoming "sluggish" symptoms in dogs and conditioning dogs after recovering from any disease; and the name "Tonic Pills" created the misleading impression that the article had unusual and general systemic conditioning and stimulating property.

DISPOSITION: 7–8–59. Consent—destruction.

NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

5864. Antiseptic nasal spray. (F.D.C. No. 43159. S. No. 51–364 P.)

QUANTITY: 28,800 individually cartoned 15-cc btls. at Chicago, Ill.

SHIPPED: 8–13–57 and 8–19–57, from Cleveland, Ohio, by Strong, Cobb & Co., Inc.

LABEL IN PART: (Btl.) "F & F Antiseptic Nasal Spray * * * Ingredients: Phenylephrine Hydrochloride 0.25% Pyrilamine Maleate 1.0% Tyrothricin 0.01% Cetyl Dimethyl Benzyl Ammonium Chloride 1:10,000 F & F Laboratories, Inc., Chicago 32, Illinois."

RESULTS OF INVESTIGATION: Analysis showed that the article contained 1 percent pyrilamine maleate as stated on the label.

LIBELED: 5–25–59, N. Dist. Ill.

CHARGE: 502(a)—when shipped and while held for sale, the labels of the article contained false and misleading representations that it was an adequate and effective treatment for sinusitis; and 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 6–22–59. Default—destruction.

DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

5865. Various drugs. (F.D.C. No. 42315. S. Nos. 32–161/2 P, 32–165/6 P, 32–168/75 P.)

QUANTITY: 1 186-capsule btl. of *Compazine Spansules*, 1 180-tablet btl. of *Nilivar Salud*, 1 370-tablet btl. of *Premarin with methyltestosterone*, 1 62-capsule box of *Panalba*, 1 180-capsule btl. of *Vascutum*, 1 185-tablet btl. of *penicillin*, 1 100-tablet btl. of *Neopenzine 300*, 1 1-oz. btl. of *Cathomycin Calcium Syrup*, 1 1-pt. btl. of *Tetrabon V Tetracycline Syrup*, 24 cartoned vials of *Remanden-100*, 6 cartoned vials of *Remanden-250*, and 4 24-tablet btls. of *Dramcillin-250* (penicillin with sulfonamides), at New York, N.Y., in possession of Theresa Pharmacy.

SHIPPED: The articles were shipped at various times in the past 5 years, prior to the filing of the libel from outside the State of New York.

RESULTS OF INVESTIGATION: The *Compazine Spansule capsules, Nilivar Salud tablets, Premarin tablets with methyltestosterone, Panalba capsules, Vascutum*

capsules, penicillin tablets, Neopenzine 300 tablets, Cathomycin Calcium Syrup, and *Tetrabon V Tetracycline Syrup* were repacked and labeled by the dealer after shipment as described above.

LIBELED: 1-2-59, S. Dist. N.Y.

CHARGE: *Cathomycin Calcium Syrup.* 501(c)—while held for sale, the strength of the article fell below that which it purported and was represented to possess, namely, that each 5 cc. contained 125 milligrams of novobiocin.

Compazine Spansule capsules, Nilivar Salud tablets, Premarin tablets, with methyltestosterone, and *Vascutum capsules.* 502(b)(2)—while held for sale, the labels of the articles failed to bear an accurate statement of the quantity of contents; and 502(e)(2)—their labels failed to bear the common or usual name of each active ingredient; and 503(b)(4)—the articles were subject to 503(b)(1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

Ramanden-100, Remanden-250, and *Dramcillin-250 tablets.* 502(l)—while held for sale, the articles were composed in part of a kind of penicillin and they were not from batches with respect to which certificates were effective since the drugs had passed their effective expiration dates.

Panalba capsules, penicillin tablets, and *Neopenzine-300 tablets.* 502(l)—while held for sale, the articles were composed in whole or in part of penicillin and they were not from batches with respect to which certificates or releases were effective pursuant to Section 507 since they were repackaged and had not been certified since repacking.

Tetrabon V Tetracycline Syrup. 502(l)—while held for sale, the article was composed in part of chlortetracycline and it was not from a batch with respect to which a certificate or release was effective pursuant to Section 507 since it was repackaged and had not been certified since repacking.

The libel also charged that a quantity of vitamin tablets was adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 1-27-59. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

DRUGS FOR HUMAN USE

5866. Betaine hydrochloride and betaine anhydrous. (F.D.C. No. 43130. S. Nos. 38-986/8 P and 39-000 P.)

QUANTITY: 2 drums of *betaine hydrochloride* and 2 drums of *betaine anhydrous* at San Jose, Calif.

SHIPPED: 10-28-58 and 1-9-59, from New York, N.Y., by Polychemical Laboratories, Inc.

LABEL IN PART: (Drum) "10 Lbs. Betaine Hydrochloride for Manufacturing, Processing or Repacking. * * * Polychemical Laboratories, Inc. * * * New York 59, N.Y.," (drum) "25 Lbs. Betaine Anhydrous Lot 211 For Manufacturing, processing or repacking * * * Polychemical Laboratories, Inc. * * * New York, N.Y."

LIBELED: 5-6-59, N. Dist. Calif.

CHARGE: 502(f)(1)—when shipped, the labeling of the articles failed to bear adequate directions for use.

DISPOSITION: 6-4-59. Default—destruction.